K040787

APR 1 4 2004

510 (k) SUMMARY

SPONSOR:	Boston Scientific Corporation One Boston Scientific Place Natick, MA 01760
CONTACT PERSON:	Janet A. McGrath Regulatory Affairs Specialist Or Lorraine M. Hanley Director Regulatory Affairs
DEVICE:	Surgical Mesh
Trade Name:	To Be Determined
Common Name:	Surgical Mesh, Polymeric
Classification:	Class II, per 21 CFR 878.3300, FTL
PREDICATE DEVICE:	Surgical Mesh (K020110)
DESCRIPTION:	The Surgical Mesh is a knitted polypropylene monofilament fiber mesh, and may be offered in a variety of sizes and shapes for use in surgical repair procedures and for use as a suburethral sling. The surgical mesh may be offered with other legally marketed devices as a convenience to the user and to facilitate device placement such as with the proposed sling configuration, which includes the knitted polymer mesh within a protective sleeve for attachment to a delivery device
INTENDED USE:	The surgical mesh is intended for treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency and to reinforce soft tissue where weakness exists in the urological, gynecological, or gastroenterological anatomy. This includes but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, reconstruction of the pelvic floor, and sacro-colposuspension
TECHNOLOGICAL CHARACTERISTICS:	The intended use and the materials of the surgical mesh are identical to the predicate device.
PERFORMANCE DATA:	The surgical mesh is identical to currently marketed surgical mesh in terms of performance characteristics, biocompatibility, and intended use. Therefore testing was not required to be repeated on the surgical mesh.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 4 2004

Ms. Janet A. McGrath
Regulatory Affairs
Boston Scientific Corporation
Urology and Gynecology Division
One Boston Scientific Place
Natick, Massachusetts 01760

Re: K040787
Trade/Device Name: Modification to Polymeric Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Polymeric surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: March 24, 2004
Received: April 1, 2004

Dear Ms. McGrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): To be determined

Device Name: To be determined

Indications For Use:

The device is intended for treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency and to reinforce soft tissue where weakness exists in the urological, gynecological, or gastroenterological anatomy. This includes but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, reconstruction of the pelvic floor, and sacro-colposuspension

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040787